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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/599,334	06/22/2000	Thomas Graf	2565/74	7641

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EXAMINER

BIANCO, PATRICIA

ART UNIT PAPER NUMBER

3762

DATE MAILED: 11/19/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/599,334

Applicant(s)

GRAF ET AL.

Examiner

Patricia M Bianco

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 11 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 1-6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 June 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5,6,8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Detailed Action*.

**DETAILED ACTION**

***Election/Restrictions***

Applicant's election without traverse of Group II, claims 7-13, in Paper No. 10 is acknowledged.

Claims 1-6 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Priority***

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

***Information Disclosure Statement***

The information disclosure statement filed 8/10/02 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

***Oath/Declaration***

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:  
Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Changes have been made to the addresses of inventors Graf and Grob, however, the changes have not been initialed.

***Specification***

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the claim limitation "***rate determining means***" of claim 1 is not supported in the specification. It is not clear, from the written description and

drawings filed, what structure specifically is responsible for determining the blood and dialysis fluid flow rates and/or the ultrafiltration rate.

Further, it is unclear if applicant's intent is to invoke 35 U.S.C. 112, sixth paragraph by the recitation of this limitation. If applicant does invoke 112, sixth paragraph, the specification must be amended to include a recitation of a "*rate determining means*" that meets the requirements of 35 U.S.C. 112, sixth paragraph. The specification should be amended pursuant to 37 CFR 1.75(d) to explicitly state, with reference to the terms and phrases of the claim element, what structure, materials, and acts perform the function recited in the claim element. (Also see **MPEP, 608.01(o)**, **MPEP 2181** (Rev. 1, Feb.2000)) *Wolfensperger*, 302 F.2d at 955, 133 USPQ at 542.)

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Based on the disclosure and drawings filed, it is unclear as to what structure performs the function of determining for determining the blood and dialysis fluid flow rates and/or the ultrafiltration rate. Is it the control unit (13) which is disclosed to preselect the flow for the pumps or the "device" (21) which actually

calculates values based on the rates? The control unit (13) is disclosed only to establish the preselected flow rates, it is not disclosed as a "determining" means.

Further, it is unclear if applicant's intent is to invoke 35 U.S.C. 112, sixth paragraph by the recitation of this limitation. If applicant does invoke 112, sixth paragraph, the specification must be amended to include a recitation of a "*rate determining means*" that meets the requirements of 35 U.S.C 112, sixth paragraph. The specification should be amended pursuant to 37 CFR 1.75(d) to explicitly state, with reference to the terms and phrases of the claim element, what structure, materials, and acts perform the function recited in the claim element. (Also see **MPEP, 608.01(o), MPEP 2181** (Rev. 1, Feb.2000)) *Wolfensperger*, 302 F.2d at 955, 133 USPQ at 542.)

Appropriate correction is required.

Claim 7 recites the limitation "the first device" in line 22 of the claim. There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 7, 8, 12, and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Bene (5,744,031). Bene discloses a dialysis system comprising a dialyzer (1) divided by a semipermeable membrane (4) into a blood chamber (2) and a dialysis chamber (3). The blood chamber has an inlet connected to an arterial blood line (5) and an outlet connected to a venous blood line (7). Since the claim is open-ended (i.e. "comprising"), the venous line is seen to be connected to the blood outlet regardless of the intervening bubble trap. Further, the claim does not require that the venous line be "directly connected" to the outlet. Therefore this limitation is met. The dialysis chamber has an inlet connected to a dialysis fluid inlet line (13) and an outlet connected to a dialysis fluid outlet line (29). A blood pump (6) is connected to the arterial, a first dialysis fluid pump (15) is connected to the dialysis inlet line and a second dialysis fluid pump (22) is connected to the dialysis fluid outlet line. Bene also discloses flow meters (24/25) measure the inflow and outflow rates of the dialysis fluid. As best can be understood by the examiner based on the specification as filed, either or both of the flow meters is equivalent to applicant's "rate determining means" since they measure or determine the dialysis fluid flow rates. Bene also discloses that the computing and control unit (26) can calculate the dialysance of the apparatus during the treatment

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session based on blood flow rate and/or dialysis liquid flow rate values sent to the control unit (see figure 1 & col. 4, line 33-col. 6, line 51). With respect to claim 8, since the computing and control unit of Bene computes values using formulas to calculate the dialysance based on values received by other monitoring devices (for example the sensors), it is the position of the examiner that the computing and control unit of Bene is equivalent to that of a computer.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 9, 10, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bene ('031). Bene discloses the invention substantially as claimed, see rejection



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supra. Bene, however, fails to disclose specifically that the computer calculates a diffusive component  $D1$ , effective blood flow  $Q_e$  (claim 9), the diffusive dialysance  $D(Q_d(t))$  for any flow rate  $Q_d(t)$  (claim 10), and the sum of the diffusive and convective dialysance  $k(Q_d(t), Q_e, Of(t))$  or the clearance from the diffusive dialysance  $D(Q_d(t), Q_e(t))$  according to their respective equations set forth in their respective claims. However, since the computing and control unit of Bene computes values using formulas to calculate the dialysance based on values received by other monitoring devices (for example the sensors), it clearly uses programmable software to perform the mathematical calculations. Therefore, the computing and control unit of Bene is clearly capable of being programmed with the required equations such that the control unit can calculate the diffusive component  $D1$ , effective blood flow  $Q_e$  (claim 9), the diffusive dialysance  $D(Q_d(t))$  for any flow rate  $Q_d(t)$  (claim 10), and the sum of the diffusive and convective dialysance  $k(Q_d(t), Q_e, Of(t))$  or the clearance from the diffusive dialysance  $D(Q_d(t), Q_e(t))$ . It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the computing and control unit of Bene to store the desired equations to calculate diffusive component  $D1$ , effective blood flow  $Q_e$  (claim 9), the diffusive dialysance  $D(Q_d(t))$  for any flow rate  $Q_d(t)$  (claim 10), and the sum of the diffusive and convective dialysance  $k(Q_d(t), Q_e, Of(t))$  or the clearance from the diffusive dialysance  $D(Q_d(t), Q_e(t))$ , since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

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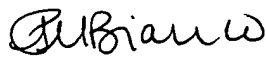
**Conclusion**

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Goldau ('199) and Sternby ('027) disclose a dialysis system having a control unit and measuring devices for calculating dialysis parameters. However, both do not qualify as prior art against the instant application since their §102(e) dates are not before the effective filing date of this application.

Any inquiry concerning the rejections contained within this communication or earlier communications should be directed to examiner Tricia Bianco whose telephone number is (703) 305-1482. The examiner can normally be reached on Monday through Fridays, alternating Fridays off, from 9:00 AM until 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The official fax numbers for the organization where this application or proceeding is assigned is (703) 872-9302 for regular communications and for After Final communications (703) 872-9303.

Tricia Bianco  
Patent Examiner  
Art Unit 3762

pmb   
November 16<sup>th</sup>, 2002